

**PATENT**

Application No. 09/914,015; Filing Date 01/28/2002

Examiner: Carlos A. Azpuru; Art Unit: 1615

Attorney Docket von Kreisler.015

**III Remarks**

**A. Claims 55–77 have been Amended to Place them in Allowable Form**

In the Action, the Examiner objected to claim 70 as dependent upon a rejected base claim. Applicants have rewritten claim 70 as an independent claim. Claim 70 sets forth the limitations of claim 54, on which claim 70 was partially dependent. Claim 70 has also been amended to address the rejections under 35 U.S.C. § 112 to claim 54. Applicants note that claim 70 was also dependent upon claim 55. However, as the Examiner also objects to claim 71 as dependent upon a rejected base claim, and claim 71 is dependent upon claim 54 and has a scope similar to that of claim 70, Applicants believe that the objection to claim 70 is addressed by incorporating into claim 70 the limitations of claim 54. Accordingly, claim 70 should be allowed.

Applicants have also amended claims 55–69 and 71–76 to make them dependent upon claim 70. As they are now dependent upon a claim that should be in condition for allowance, claims 55–69 and 71–76 should be allowed.

**B. Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claim 54 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In support of this rejection, the Examiner stated that claim 54 is indefinite in that the metes and bounds of the claimed colloid-forming Markush Group are not particularly set out since the group includes “modified” polysaccharides and polypeptides. Applicants have amended claims 54 and 70 to replace the term “*modified*” with the term “*substituted*.”

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The Examiner has also stated that claim 54 is indefinite because “the Markush [G]roup of bioactives contains ‘Parkinson[‘]s remedies and other remedies against extrapyramidal disturbances.’” These other remedies make the metes and bounds of the claimed Markush Group indefinite. Applicants have amended claims 54 and 70 to replace the Examiner’s quoted phrase with the phrase “Parkinson’s and other degenerative diseases.”

Applicants submit that the above-referenced amendments to claims 54 and 70 overcome the rejections of claim 54 under 35 U.S.C. § 112, second paragraph.

**C. Rejections Under 35 U.S.C. § 102(b)**

In view of the amendments to claims 55–76, the rejections to claims 54–62, 67–69, 74 and 75 under 35 U.S.C. § 102(b) are addressed in regard to the remaining claim 54.

Claims 54–62 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Japanese Patent Publication JP 2304023 (JP’023). The Examiner has provided the following reason in support of this rejection:

JP’023 disclose[s] the combination of lysine and a colloid forming macromolecule. Specifically, hydroxyethyl starch and dextran are recited (see Abstract). The molecular weight of hydroxyethyl starch is listed as between 40000 and 400,000. The molecular weight of dextran is recited as between 7000 and 40000. Given that the claimed hydrocolloids are used for the same art recognized purpose, and fall within the same molecular weight range, the degree of substitution for each is considered inherent to the composition as claimed. The instant claims are therefore anticipated by JP’023.

JP’023 appears to relate to a stable powder preparation for injection containing aspirin DL-lysine and 10 to 500 mg/g of hydroxy ethyl starch or dextran as a stabilizer. JP’023 also discloses that “[t]he gas in the drug container is substituted with nitrogen gas.”

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It appears that JP'023 is injected in the form of a *stable powder preparation* with nitrogen gas being used to facilitate the injection process (*emphasis added*). In contrast, Applicants' claim 54 is to an *injectable aqueous medical solution* (*emphasis added*). As JP'023's stable powder preparation is a solid, it cannot anticipate Applicants' claimed aqueous medical solution. Accordingly, the rejection of claim 54 under 35 U.S.C. § 102(b) as anticipated by JP'023 is untenable and should be withdrawn.

The Examiner has rejected claims 54–55, 68, 69 and 75 under 35 U.S.C. § 102(b) as being clearly anticipated by Published European Patent Application No. EP 0193917 (EP'917). The Examiner has provided the following reason in support of the rejection:

EP'917 disclose[s] a composition for parenteral administration which includes growth hormones as well as water soluble carbohydrate polymers including detrains, starches and cellulose (see abstract; page 3, lines 9–11). These polymers are chosen for their colloidal characteristics (see page 3, line 23). Since applicant is using the same polymers, for the same art recognized colloidal properties, the colloid osmotic pressure is an inherent property of the solutions utilizing said polymers. The instant claims are clearly anticipated by EP'917.

EP'917 is described as relating “to compositions of water dispersible and water soluble carbohydrate polymers and biologically active macromolecules of growth hormones, somatomedins, growth factors, and other biologically active fragments which are suitable for parenteral administration” and “to a method for increasing and for maintaining increased levels of growth hormone in the blood of treated animals for extended periods of time, increasing weight gains in animals and increasing milk production of lactating animals by the administration of the compositions of the invention.” (See Abstract).

Applicants' claim 54 is directed to an injectable *medicinal solution* comprising (i) at least one *pharmaceutically active ingredient* and (ii) colloid-forming macromolecules. In

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other words, the colloid and not the active pharmaceutical ingredient forms the macromolecule. As noted above, EP'917 is directed to carbohydrate polymers and *biologically active macromolecules*, which is the direct opposite of the claim 54 solution. In view of these differences, EP'917 does not anticipate claim 54.

Accordingly, the rejection of claim 54 under 35 U.S.C. § 102(b) over EP'917 should be withdrawn.

The Examiner has also rejected claims 54, 55, 67 and 74 under 35 U.S.C. § 103(b) as being clearly anticipated by French Patent Publication No. 2,296,429 (FR'429). The Examiner has provided the following reason in support of the rejection:

FR'429 [discloses] an injectable composition comprising immuoglobulins. Page 1, lines 1–30. This is done in the presence of hydrocolloids as listed at page 2, lines 23–25. These include gelatin, dextran, albumin, and polyols. The instant claims are clearly anticipated.

FR'429 relates to a method of purifying gamma globulin that includes the step of dissolving a precipitated gamma globulin in an aqueous solution containing a concentration of from 1 to 30% of a hydroxyethyl starch having a molecular weight of 1000 to 900,000. This dissolving step is followed by the step of recovering from the solution gamma globulin substantially free of anti-complementary activity. (*See* page 1, lines 82–92).

Accordingly, the French patent produces a purified gamma globulin containing *no* hydroxyethyl starch or any other colloid-forming macromolecule. In contrast, Applicants' claim 54 is directed to an injectable aqueous medicinal solution comprising (i) at least one pharmaceutically active ingredient *and* (ii) colloid-forming macromolecules. Hence FR'429, in fact, teaches away from Applicants' claimed solution.

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Accordingly, the rejection of claim 54 under 35 U.S.C. § 102(b) over FR'429 is untenable and should be withdrawn.

**D. Disposition of Claim 77**

Although the Action identifies claim 77 as pending, it was not objected to or rejected. In fact, Applicants had canceled claim 77 in the Preliminary Amendment filed as part of the national phase filing of the Application.

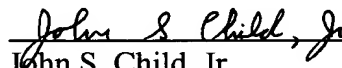
**IV Conclusion**

It is believed that the above Amendment and Remarks constitute a complete response and that all matters raised in the Action have been addressed. A Notice of Allowance in the next Office Action is therefore requested. The Examiner is requested to telephone the undersigned attorney about any matters that can reasonably be expected to be resolved in a telephone interview and are believed to impede the allowance of the pending claims of Application No. 09/914,015.

Respectfully submitted,

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Date: August 20, 2004

  
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